



Patent Settlement Agreements: A Generic Perspective

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- **Patent settlements a focus of enforcement since the EU Sector Inquiry in '09**
- **2 EU Monitoring Reports, July '10 and '11**
- **Several ongoing investigations**
 - Servier
 - Lundbeck
 - GSK/Generics
 - J&J/Sandoz (?)

‘some patent settlements in the pharmaceutical sector may prove to be problematic from a competition law perspective. Of particular interest are settlements that may lead to a delay of generic entry in return for a value transfer (e.g. a payment) by the originator company to the generic company’

2nd EU Monitoring Report

‘as is shown by the enforcement action of the USA competition authorities, in particular the Federal Trade Commission, it might also be argued that settlements contain arrangements that could fall within the scope of competition rules’

EU Sector Inquiry Report

“it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent’s effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market.”

In re Cardizem (6th Cir)

“As a matter of economics, it will generally be most profitable if the brand and the generic firm avoid the possibility of competition and share the resulting monopoly profits”

Michael Kades, FTC

“[If] the patent holder makes a substantial payment to the challenger as part of the [settlement] deal, absent proof of other offsetting considerations, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable compromise”

Schering-Plough

Continued litigation would “yield a greater prospect of competition”

FTC v Cephalon

- **Settlement presumed unlawful if**
 - there is a substantial reverse payment
 - generic entry is not immediate, and
 - there is no proof of any motive for the payment other than delayed generic entry

- **Consistently reject FTC approach**
 - *Schering-Plough v. FTC* (11th Cir)
 - *In re Ciprofloxacin* (Fed. Cir)
 - *In re Ciprofloxacin ('Arkansas Farmers')* (2nd Cir)
 - *FTC v Watson* (11th Cir)
- **With limited exceptions**
 - generic entry restricted beyond scope/term of patent –
In re Cardizem (6th Cir)
 - sham litigation or fraud

- **Settlements are in the public interest**
- **No settlement may have been possible absent reverse payment**
- **No anticompetitive effect ('You can't pay them all off')**
- **Difficulties in identifying value transfers**
- **Antitrust trials not the appropriate forum for settling patent disputes**

- **It really matters whether or not the Commission adopts the FTC's general presumption of illegality:**
 - reverse payments very difficult to justify with it
 - most cases will be very difficult to make without it
- **The Commission should not adopt the presumption**
- **Some cases will remain easy either way**
 - generic entry restricted outside patent scope
 - shams and fraud

- **No presumption of validity for settlements**
 - *Bayer v Sülhöfer*
- **History of ‘second guessing’ IP outcomes**
 - *Toltecs-Dorcet*
- **Relatively non-interventions Courts**
- **Broad approach to potentially problematic settlements**

- **Two main criteria for classifying settlements**
 - limitation on the generic company's ability to market its own medicine
 - a value transfer from the originator to the generic company
- **Limitation broadly defined**
 - includes: no challenge clauses, non-compete clauses, licenses and distribution agreements
- **Value transfer broadly defined**
 - cash, distribution agreements, “side deals”

- **Sector Inquiry Final Report, July ‘09**
 - “any assessment of whether a certain settlement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis”
- **Dominik Schichels, Nov ‘09**
 - Commission “will not take the view *per se* that patent settlements are probably illegal”

- **Dominik Schichels, Oct '10**
 - “we do not like to see a value transfer, as without it, the companies would likely have found a different date”
- **Commissioner Almunia, Oct '11**
 - “Paying a competitor to stay out of the market is a restriction of competition that the Commission will not tolerate”

- **May '03 – Boehringer scientist photographs poster of Almirall substance (anticholinergic)**
- **July '03 – Boehringer submits 3 combination patents covering Almirall substance + combinant**
- **Each patent similar – 1st starts**
 - “an unexpectedly beneficial therapeutic effect can be observed in the treatment of inflammatory and/or obstructive diseases in the anticholinergic ... is used with one or more PDE IV inhibitors”
- **Feb '07 – Almirall complains to European Commission**

- **Jan '09 – UK High Court finds**
 - Boehringer 1st patent invalid on grounds of obviousness and insufficiency
 - “observed” statement in patent is “false”
- **July '09 – Commission re-launches investigation**
 - “main focus” is whether Boehringer obtained patents by providing misleading information
- **July '11 – Commission closes file having “encouraged” settlement between parties**
 - “As Boehringer agreed to remove the alleged blocking positions ... the Commission no longer needs to pursue the case”

- **Be wary of time wasting**
- **Avoid**
 - limits on generic entry outside the patent's scope (time, product, geography)
 - cash payments
 - side deals with no commercial rationale
 - unhelpful internal documents
- **Do**
 - permit generic entry before patent expiry
 - consider arrangements that benefit both sides

Thank you!

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